Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2022-12-14 - 10:09
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2022-12-14 - 10:39
Approved:	QA	Elin Andersson - ELIAND	2022-12-14 - 16:14
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:13

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Product description:

Provox Dilator is a stepwise tapered, about 140 mm (5.5 inch) long solid curved rod made of medical grade silicone. The diameter is 15 Fr at the tip and increases to 24 Fr. At the end of each diameter step, i.e. 18, 20 and 22 Fr respectively, a small retaining collar is made to prevent the dilator from gliding back to the thinner section. The dilator also has a retainer strap with medallion intended to reduce the risk of accidental aspiration.

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VAT no. SE556268760701

Product Information

Document ID:	PF005-01-TechInfo	**Edition:**	09

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (MDD 93/42/EEC) IIa (2.1 Rule 5)

Intended Use: The Provox Dilator is intended for upsizing smaller tracheo-esophageal (TE) punctures (i.e. from 16 Fr diameter) to allow fitting of Provox voice prostheses, or upsizing a shrunken puncture to an adequate diameter, i.e. after loss of a voice prosthesis. The dilator may also be used for temporary blockage of a TE puncture or to temporarily prevent such from shrinkage. It is only intended to be used by physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Use specifications:

Intended medical indication
Laryngectomized patients with a tracheo-esophageal (TE) fistula.

Intended patient population
Male and female.
Typical average age for a laryngectomy is 65 years.

Intended usage
The Provox Dilator is intended for upsizing smaller tracheo-esophageal (TE) punctures (i.e. from 16 Fr diameter) to allow fitting of Provox voice prostheses, or upsizing a shrunken puncture to an adequate diameter, i.e. after loss of a voice prosthesis. The dilator may also be used for temporary blockage of a TE puncture or to temporarily prevent such from shrinkage. It is only intended to be used by physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Intended part of the body/type of tissue applied to or interacted with
Stoma; tissue.

Intended user profile
Physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Intended conditions of use
Hospital use.

Contraindications: The device is not intended to be used by patients that have not received adequate training by their clinician.

The device is not intended to be used for puncture dilation at the time of surgical creation of the puncture.

Do not use the device in case of a small tracheostoma where the dilator could obstruct breathing.

CE Mark: Yes. Device is CE-marked.

GMDN code: 62125 (Tracheoesophageal fistula dilator)

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Product Information

Sterilization:	Non-sterile, sterilizable by steam.
Raw material:	Silicone with blue masterbatch.
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	5 years after manufacturing.
Packaging:	The Provox Dilator is separately packed together with instructions for use in a plastic bag made of polyethylene and thereafter packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0007-BR

REF	Name	UDI-DI
7211	Provox® Dilator	7331791000850

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Document No: 10000038301 Edition: 09 Release date: 2023-03-16

Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Reviewed:	QA	Abdallah Almashharawi - ABDALM	2022-12-12 - 16:36
Approved:	QA	Elin Andersson - ELIAND	2022-12-14 - 08:42
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:13

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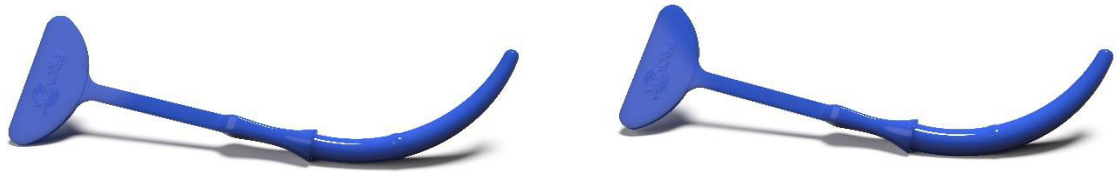

Product description:

Provox Dilator 17 and Provox Dilator 20 are tapered curved silicone rods used for dilating (increase the diameter of) TE punctures. Provox Dilator 17 shall be used with Provox voice prostheses with an outer diameter of 17 Fr and Provox Dilator 20 with outer diameter 20 Fr. The dilator shall only be used and be prescribed for patient use, by clinicians trained in the care and rehabilitation of laryngectomized patients. The Provox Dilator 17 and 20 have a retainer strap with medallion intended to reduce the risk of accidental aspiration

Product Information

Document ID: PF005-02-TechInfo **Edition:** 08

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (MDD 93/42/EEC) IIa (2.1, Rule 5)

Intended Use: The Provox Dilator 17 and 20 are used for dilating tracheo-esophageal (TE) punctures that shrinks very fast or are too narrow to insert the selected Provox voice prosthesis. The Dilator may also be used to temporarily block or stent the TE puncture

Use specifications:

Intended medical indication
Laryngectomized patients with a tracheo-esophageal (TE) fistula.

Intended patient population
Male and female.
Typical average age for a laryngectomy is 65 years.

Intended usage
The Provox voice prosthesis system is intended for use of prosthetic voice restoration after total laryngectomy. The Provox Dilator 17 and 20 are used for dilating tracheo-esophageal (TE) punctures that shrinks very fast or are too narrow to insert the selected Provox voice prosthesis. The Dilator may also be used to temporarily block or stent the TE puncture.

Intended part of the body/type of tissue applied to or interacted with
Stoma; tissue.

Intended user profile
For Home Care Use the Dilator is intended for single patient re-use, and may only be used as part of the Provox NID system. It shall only be used by patients with sufficient manual dexterity, acceptable vision and satisfactory cognitive ability. The Dilator shall always be prescribed by a clinician trained in the dilation procedure. For Professional Use the Dilator may be re-used by a clinician in clinic and shall then be re-sterilized between patients.

Intended conditions of use
Hospital and home care use.

Contraindications: The device is not intended to be used by patients that have not received adequate training by their clinician. The device is not intended to be used for puncture dilation at the time of surgical creation of the puncture. Do not use the device in case of a small tracheostoma where the dilator could obstruct breathing.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62125 (Tracheoesophageal fistula dilator)

Sterilization: Non-sterile, sterilizable by steam.

Raw material: Silicone with blue masterbatch.

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Product Information

Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	5 years after manufacturing.
Packaging:	The Provox Dilator is separately packed together with instructions for use in a plastic bag made of polyethylene and thereafter packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0007-BR

REF	Name	UDI-DI
7122	Provox Dilator 17	07331791000393
7123	Provox Dilator 20	07331791000409

Provox Dilator 17 (REF 7122)

Provox Dilator 20 (REF 7123)

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Karin Olsson - KAROLS	2022-10-06 - 15:37
Reviewed:	QA	John Wennborg - JOHWEN	2022-10-07 - 16:29
Approved:	DD	Diana Tieger - DIATIE	2022-10-11 - 08:19
Released:	QA	Abdallah Almashharawi - ABDALM	2023-02-22 - 07:32

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Product Information

Provox® Flush

Product description:

The Provox Flush device has two components, the Flushing Tube and the Flushing Bladder, which should be assembled by the user. The tip has been designed to fit all sizes of Provox Prosthesis. Squeezing the bladder and there after releasing it allows the flush to be filled with water or air. After sealing the flush against the prosthesis, another squeeze of the bladder will flush water (or air) through the prosthesis. The Flushing tube is bendable to facilitate the best possible seal regardless of tracheoesophageal (TE)-puncture angle.

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Document Number: XV-0542650 Status: Effective Version: 1.0
Name: PF006-01-TECHINFO

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Product Information

Document ID:	PF006-01-TechInfo	**Edition:**	11

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745
Class I, Rule 5

Intended Use:
The Provox Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes. The Flush is intended for both home and clinical use by patient or clinician.

Use specifications:

Intended medical indication
Laryngectomized patients that use voice prostheses, which need cleaning.

Intended patient population
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage
Single patient multiple use, Over-the-counter.

Intended part of the body/type of tissue applied to or interacted with:
Mucosal membrane.

Intended user profile
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Replacement rate: Max usage for 12 months.

Contraindications:
None

CE Mark:
Yes. Devices are CE-marked

GMDN code:
62096 (Tracheoesophageal speech valve irrigation device)

Sterilization:
Non-sterile.

Raw material:
Flushing tube: Polypropylene (PP) with blue masterbatch
Flushing Bladder: Silicone.

Latex information:
Not manufactured with natural rubber latex

Biological origin:
The device is not manufactured with materials derived from human or animal source.

Handling and storage:
Store the product dry and away from sunlight at room temperature.
Excursions permitted between 2°C - 42°C.

Waste handling and disposal:
Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components:
None

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Product Information

Expiration date: 5 years after manufacturing.

Packaging: Provox Flush is separately packed in a plastic bag and then, together with Instructions for use, packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0001-RK

REF	Name	UDI-DI
8109	Provox Flush	07331791005930
8109-18	Provox Flush	07331791013843

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox NID	7331791-VPS-0-00I-0000-NQ
Provox ActiValve	7331791-VPS-0-00I-0000-NQ

Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2023-06-27 - 16:13
Reviewed:	QA	Niki Svensson - NIKSVE	2023-06-27 - 16:21
Approved:	DD	Christian Engelhardt - CHRENG	2023-06-30 - 14:59
Released:			

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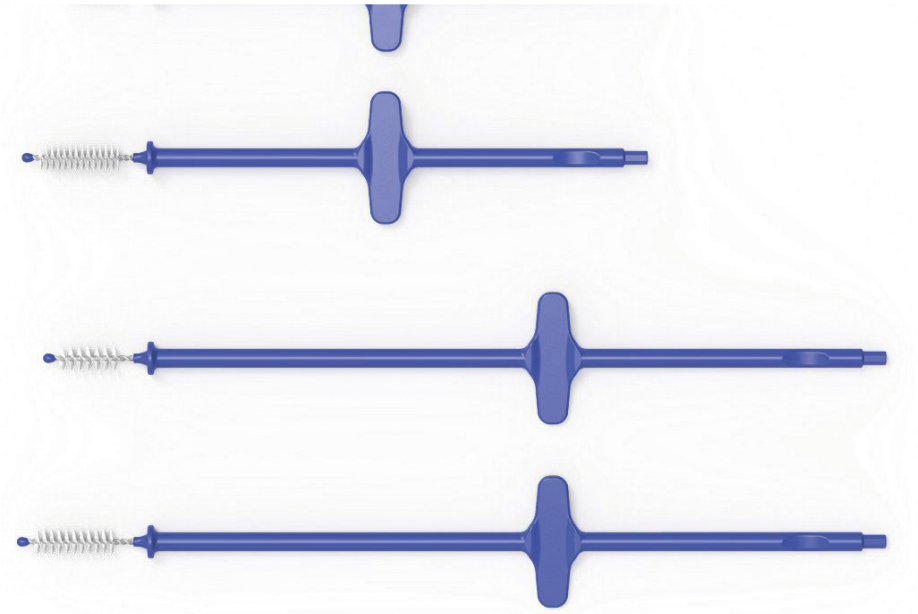

7225	27,5	105
8404 8404-18	22	155
8425 8425-18	27,5	155

Product description:

The Provox Brush is a device helping to clean Provox voice prostheses or fenestration holes in LaryTube or can be used for application of Flourosilicone oil or Anti-Candida medication into Provox voice prostheses. The distal end of the brush can help to place Provox Plug and Provox Vega Plug into the voice prosthesis.

The brush is intended for single patient re-use and is intended for both home and clinical use by patient or clinician. Maximal use 30 days.

Document No: 10000038302 Edition: 13 Release date: 2023-07-14

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Product Information

Document ID:	PF007-01-TechInfo	**Edition:**	13

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 Class I, Rule 5

Intended Use: Provox Brush is a single patient use device intended for cleaning Provox voice prostheses, for insertion of Provox Plug and Provox Vega Plug, for applying lubricant and anti-candida agents and for cleaning of fenestration holes on Provox LaryTubes. The product is intended for use by the patient.

Use specifications: Intended medical indication:

For cleaning Provox Voice Prosthesis/LaryTube/Life LaryTube, insertion tool for Provox Plug, applying tool lubricant/agent in laryngectomized patients.

Intended patient population:

Patients of any age.

Cognitive ability, by a clinician judged as sufficient.

Manual dexterity, by a clinician judged as sufficient.

Intended usage:

Single patient- multiple use, Over-the-counter

Intended part of the body/type of tissue applied to or interacted with:

Mucosal membrane

Intended user profile:

The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use:

Environment: Home use (keep away from sunlight and keep dry).

Frequency of use: Continuous use.

Replacement rate: Max 30 days, then discarded.

Contraindications: No contraindications.

CE Mark: Yes. Devices are CE-marked

GMDN code: 62095 (Airway device cleaning utensil, invasive)

Sterilization: Non-sterile

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Product Information

Raw material:	Brush head: Stainless steel, Polyamide (PA) Handle/Tip: Polypropylene (PP) with blue masterbatch. Soft Part: Thermoplastic elastomer (TPE)
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	5 years after manufacturing.
Packaging:	6 pcs packed in a tamperproof plastic bag together with Instructions for Use.

Product Information

Devices under Basic UDI-DI:

REF	Name	UDI-DI
7204	Provox Brush	07331791000775
7225	Provox Brush XL	07331791001451
8404	Provox Brush Long	07331791015588
8425	Provox Brush Long XL	07331791015595
8404-18	Provox Brush Long	07331791016431
8425-18	Provox Brush Long XL	07331791016448

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal	7331791-VPS-0-0EI-0004-33
Provox Vega Puncture Set	7331791-VPS-0-0EI-0003-2Y
Provox NID	7331791-VPS-0-00I-0000-NQ
Provox ActiValve	7331791-VPS-0-00I-0001-NT
Provox ActiValve Lubricant	7331791-GEN-A-000-0004-EJ
Provox LaryTube Fenestrated	7331791-LTU-0-000-0002-3E
Provox Life LaryTube Fenestrated	7331791-LTU-0-000-0004-3L
Provox Plug/Provox Vega Plug	7331791-VPS-A-000-0004-RU

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Issued:	QA	Sara Dahl - X-SARDAH	2021-11-19 - 18:38
Reviewed:	QA	John Wennborg - JOHWEN	2021-11-22 - 11:42
Approved:	DD	Jon Berg - JONBER	2021-11-22 - 14:31
Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:52

This document has been electronically signed by the persons above.

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Product Information

Provox® Measure

Product description:

Reusable instrument for measuring the length (corresponding to voice prosthesis size) of TE punctures. The single-use flanges of Provox Measure can be attached to the instrument in two different ways, facilitating measurement of fistulas made for different voice prosthesis diameters.

Document No: 10000038338 Edition: 11 Release date: 2021-12-10

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Product Information

Document ID:	PF010-01-TechInfo	**Edition:**	11

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745
Class I, Rule 5

Intended Use:
The Provox Measure is intended for sizing the length (corresponding to voice prosthesis length) of tracheoesophageal (TE) punctures.

Use specifications:
Intended medical indication:
For measuring the length (corresponding to voice prosthesis length) of the tracheoesophageal (TE) punctures in laryngectomized patients.
Intended patient population:
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.
Intended usage:
Provox Measure is sterilizable. Provox Measure Flanges are for single use.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane in the tracheoesophageal puncture.
Intended user profile:
The product is supposed to be handled by physicians, trained nurses, SLPs and clinicians.
Intended conditions of use:
Hospital use. Not continuous use.

Contraindications:
Do not use the device on punctures of diameter less than 20 Fr as this may cause damage and/or bleeding of the puncture.
The device is not intended to be used at the time of surgical creation of the puncture.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62126 (Tracheoesophageal fistula gauge)

Sterilization:
Non-Sterile, The Provox Measure instrument is sterilizable by steam.

Raw material:
Rod: Stainless steel
Tube: Polyoxymethylene (POM)
Flange: Silicone with blue masterbatch

Latex information:
Not manufactured with natural rubber latex

Biological origin:
The device is not manufactured with materials derived from human or animal source.

Handling and storage:
Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal:
Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

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Product Information

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging:

7270 Provox Measure:
The Provox Measure instrument and 6 pieces Provox Measure Flanges are packed separately in plastic bags together with instructions for use (90727) and cleaning/sterilization instructions (10025-1). The bags are packed in a cardboard box.

7271 Provox Measure Flanges:
The Provox Measure Flanges are packed 5 pieces in a plastic bag together with 1 instructions for use (90727).

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0005-BK

REF	Name	UDI-DI
7270	Provox Measure	07331791001710
7271	Provox Measure Flanges	07331791001727

Atos Medical AB compatible products:

None.

Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2023-06-19 - 14:16
Reviewed:	QA	Niki Svensson - NIKSVE	2023-06-19 - 15:10
Approved:	DD	Christian Engelhardt - CHRENG	2023-06-20 - 09:14

This document has been electronically signed by the persons above.

Provox® Plug

Provox® Vega Plug

Product description:

The Provox Plug / Provox Vega Plug is a first-aid tool for temporarily stopping leakage through the voice prosthesis. The device is inserted into the opening of the Provox / Provox Vega voice prosthesis and hence blocking any leakage through the valve. The medallion end can be taped to the skin if desired.

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atosmedical.com

Product Information

Document ID:	PF012-01-TechInfo	**Edition:**	09

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification:
MDD 93/42/EEC
IIa (2.1, Rule 5)

Intended Use:

Provox Plug:
Provox Plug is intended to seal the inner lumen of Provox voice prosthesis, Provox2 voice prostheses and Provox ActiValve and therefore stop leakage of both air and fluids through the voice prosthesis.

Provox Vega Plug:
Provox Vega Plug is intended to seal the inner lumen of Provox Vega voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis.

Use specifications:

Intended medical indication:
Provox Plug / Provox Vega Plug is a first-aid tool for temporarily stopping leakage through an indwelling Provox voice prosthesis in laryngectomized patients.

Intended patient population:
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage:
Single patient multiple use, Over-the-counter.

Intended part of the body/type of tissue applied to or interacted with:
Introduced in the lumen of a voice prosthesis that is placed in a TE puncture.

Intended user profile:
Head and Neck Surgeon for placement of voice prosthesis. Trained clinician (e.g. physician, SLP) for replacement of voice prosthesis.

Intended conditions of use:
Home use (normal environment without any hygienic or environmental restrictions regarding temperature, moisture etc.) when necessary.

Contraindications:
There are no known contraindications for use or replacement of the Provox Plug / Provox Vega Plug among patients already using prosthetic voice rehabilitation.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62119 (Tracheoesophageal speech valve occlude, non-valved).

Sterilization:
Non-sterile.

Raw material:
Silicone

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Product Information

Latex information:	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	5 years after manufacturing.
Packaging:	Provox Plug / Provox Vega Plug is separately packed in a LDPE plastic bag together with one Provox Brush and two instructions for use (Provox Plug/Provox Vega Plug and Provox Brush).

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0004-RU

REF	Name	UDI-DI
7205	Provox Plug	07331791000782
8119	Provox Vega Plug 17	07331791005947
8129	Provox Vega Plug 20	07331791005954
8139	Provox Vega Plug 22.5	07331791005961
8119-18	Provox Vega Plug 17	07331791013775
8129-18	Provox Vega Plug 20	07331791013782
8139-18	Provox Vega Plug 22.5	07331791013799

Provox Plug (one size)

Provox Vega Plug (comes in three different sizes)

Atos Medical AB compatible products:

Range	Plug	Vega Plug	BASIC UDI-DI
Provox ActiValve	X		7331791-VPS-0-00I-0001-NT
Provox NID	X		7331791-VPS-0-00I-0000-NQ
Provox Vega		X	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal		X	7331791-VPS-0-0EI-0004-33
Provox2 Voice Prosthesis	X		7331791-VPS-0-0EI-0005-36
Provox LaryClip		X	7331791-LTU-A-000-0001-JT
Provox TubeHolder		X	7331791-GEN-A-000-0000-E6

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sofia Thomasson - SOFTHO	2022-09-07 - 12:01
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-09-07 - 12:54
Approved:	DD	Diana Tieger - DIATIE	2022-09-09 - 08:26

This document has been electronically signed by the persons above.

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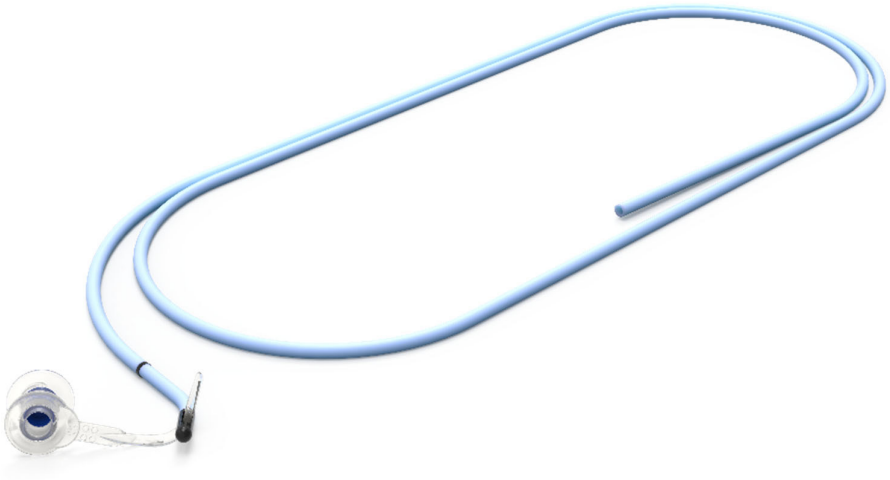
Product Information

Provox® GuideWire



Product description:

Provox GuideWire is a sterile single use insertion device intended for placement of a sterile Provox indwelling voice prosthesis, and for retrograde replacement of a Provox indwelling voice prosthesis. Provox GuideWire consists of a tube made of a PVC plastic material and a connector for attachment of a Provox indwelling voice prosthesis safety strap made of nylon plastic material (Polyamide).

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Product Information

Document ID: PF024-01-TechInfo **Edition:** 01

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class IIa (Rule 6)

Intended Use: The Provox GuideWire is a sterile single use insertion device intended for placement of a sterile Provox indwelling voice prosthesis after total laryngectomy (primary or secondary puncture), or for retrograde replacement of a Provox indwelling voice prosthesis.

Use specifications:

Intended medical indication
To facilitate voice rehabilitation in laryngectomized patients.
Intended patient population
Laryngectomized of any age.

Intended usage
Single use. Prescription only.

Intended part of the body/type of tissue applied to or interacted with:
Primary interaction (transient): Tracheoesophageal wall.
Secondary interaction (transient): Trachea, esophagus, pharynx, mouth.

Intended user profile
Trained clinician (e.g., ENT surgeon, SLP) for placement of voice prosthesis.
Trained clinician (e.g., physician, SLP) for replacement of voice prosthesis.

Intended conditions of use
Placement of voice prosthesis is performed at the time of, and in the environment of, the procedure of tracheoesophageal puncture, e.g., the operating theatre or in an outpatient clinic.
Replacement of voice prosthesis is performed in outpatient hospital settings, on average 4 times per year.

Contraindications: Do not use if the patient has anatomical abnormalities, e.g., significant pharyngeal stenosis above the puncture site or severe trismus. Significant pharyngeal stenosis may preclude insertion of the voice prosthesis. Severe trismus may preclude proper protection of the pharyngeal wall during secondary puncture leading to harm of the esophageal tissue.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 65394 Tracheoesophageal speech valve guidewire

Sterilization: EO-sterilization

Raw material: PVC Tubing: Polyvinyl chloride (PVC).
GuideWire Joint and GuideWire Tip: Polyamide (PA) and black masterbatch.

Latex information: Not manufactured with natural rubber latex.

Biological origin: The device is not manufactured with materials derived from human or animal source.

Product Information

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging: The Guidewire is packed in a sterility bag made of paper and polyester/polypropylene laminate. It is then packed in a cardboard box together with instructions for use.

Devices under Basic UDI-DI: 7331791-VPS-A-OEO-0006-5Z

REF	Name	UDI-DI
7215	Provox GuideWire	7331791000867

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	7331791-VPS-0-0E0-0002-N2
Provox Vega XtraSeal	7331791-VPS-0-0E0-0004-N8
Provox2 Voice Prosthesis	7331791-VPS-0-0E0-0005-NB
Provox ActiValve	7331791-VPS-0-000-0001-A3

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Released:	QA	Elin Andersson - ELIAND	2022-05-25 - 07:47

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Product Information

Provox® XtraFlange

Product description:

Provox XtraFlange is a white silicone washer that is intended to be placed between the tracheal flange of the prosthesis and the tracheal mucosa. It provides an extra seal against periprosthetic leakage through the adherence of the thin silicone sheet to the tracheal mucosa.

The device is supplied sterile and is intended for single use only.

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Product Information

Document ID: PF056-01-TechInfo **Edition:** 06

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (MDD 93/42/EEC) IIb (2.1, rule 5)

Intended Use: Provox XtraFlange is a silicone washer intended to reduce periprosthetic leakage that is detected on patients using indwelling Provox voice prostheses. Placement is performed by a medical doctor or a trained medical professional in accordance with local or national guidelines.

Use specifications:

Intended medical indication

Reduce periprosthetic leakage on patients using indwelling Provox voice prostheses.

Intended patient population

Age: Typically, but not limited to patients above 60 years.

Gender: Male and Female with a bias towards males

Weight: Representative of overall human population

Health and condition: All health and condition states

Intended usage;

Single use, Prescription only.

Intended part of the body/type of tissue applied to or interacted with:

Primary interaction (short and long term): Tracheoesophageal wall, tracheal side.

Secondary interaction (transient): Trachea, Esophagus, Pharynx.

Intended user profile

Insertion of the Provox XtraFlange, typical an SLP or other clinical professional experienced in voice prosthesis maintenance.

Intended conditions of use

At the time of, and in the enviroment of, voice prosthesis maintenance and/or change in a clinical setting.

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Product Information

Contraindications: Provox XtraFlange shall NOT be used:

- in patients in whom the tracheoesophageal (TE) puncture is too wide to ensure adequate retention of the Provox voice prosthesis. A too wide puncture may increase the risk of dislodgement and aspiration of the device and/ or the voice prosthesis. Provox XtraFlange will NOT increase retention of the prosthesis.

- on Provox NiD or other voice prosthesis of any other brands. It may increase the risk of dislodgement and aspiration of Provox XtraFlange and/or voice prosthesis

CE Mark: Yes. Devices are CE-marked.

GMDN code: 42533 (Tracheoesophageal speech valve, indwelling)

Sterilization: EO-sterilization

Raw material: Silicone with 10 % barium sulphate (BaSO4)

Latex information: Not manufactured with natural rubber latex

Biological origin: The device is not manufactured with materials derived from human or animal source.

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging: The product is packed in a blister package made of PETG film and with a Tyvek (spun-bounded polyethylene) top film. It is then packed in a cardboard box together with a instruction for use. Finally tamper proof.

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Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-0E0-0008-67

REF	Name	UDI-DI
7275	Provox XtraFlange 22.5	07331791006920
7276	Provox XtraFlange 20	07331791006937
7277	Provox XtraFlange 17	07331791006944

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox ActivValve	7331791-VPS-0-00I-0001-NT
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal	7331791-VPS-0-0EI-0004-33

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Released:	QA	Elin Andersson - ELIAND	2021-07-07 - 13:42

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Product Information

Provox® Capsule

Product description:

The esophageal flange of the voice prosthesis is folded into the Capsule and the voice prosthesis is placed in the TE-puncture. The voice prosthesis is manually kept in place, while the patient is drinking water until the Capsule is dissolved and the esophageal flange have unfolded on the esophageal side of the TE-puncture.

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Product Information

Document ID:	PF073-01-TechInfo	**Edition:**	06

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox Capsule is a single use accessory for anterograde insertion of a standard voice prosthesis by a clinician into the tracheoesophageal puncture of laryngectomized patients.

Use specifications: The holder is disconnected from the Capsule and discarded. The esophageal flange of the voice prosthesis is folded into the Capsule and the voice prosthesis is placed in the TE-puncture. The voice prosthesis is manually kept in place, while the patient is drinking water until the Capsule is dissolved and the esophageal flange have unfolded on the esophageal side of the TE-puncture.

Contraindications: None

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62134 (Tracheoesophageal device insertion cap)

Sterilization: Non-Sterile

Raw material: Hypromellose, (HPMC).

Latex information: Not manufactured with natural rubber latex.

Biological origin: The device is not manufactured with materials derived from human or animal source.

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 3 years after manufacturing.

Packaging: 15 pcs Provox Capsules are packed in a plastic container and then in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0000-RG

REF	Name	UDI-DI
7794	Provox Capsule 16Fr	07331791008993
7795	Provox Capsule 17Fr	07331791009006
7796	Provox Capsule 20Fr	07331791009013
7797	Provox Capsule 22.5Fr	07331791009020

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	7331791-VPS-0-0EI-0002-2V

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Approved:	DD	Jon Berg - JONBER	2022-01-31 - 09:18
Released:	QA	Elin Andersson - ELIAND	2022-02-22 - 09:01

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Product Information

Provox® TwistLock

Product description:

The Provox TwistLock is placed on the top of the Insertion System folding tool and securely locked by twisting it clockwise. The TwistLock is keeping the folding tool in a closed position to facilitate easy insertion of a voice prosthesis into a Provox Capsule. After the voice prosthesis is placed into the Capsule, TwistLock is to be removed and discarded.

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Product Information

Document ID:	*PF100-00-TechInfo* **Edition:** *05*
Manufacturer:	*Atos Medical AB* *Kraftgatan 8* *SE-242 35 Hörby,Sweden*
Classification: (EU) 2017/745	*Class I, Rule 1*
Intended Use:	*Provox TwistLock is a single use Provox Insertion System accessory for easier loading of Provox Vega Voice Prosthesis into Provox Capsule by clinician.*
Use specifications:	**Intended medical indication** *For voice rehabilitation in laryngectomized patients.* **Intended patient population** *Patients of any age.* *Cognitive ability, by a clinician judged as sufficient.* *Manual dexterity, by a clinician judged as sufficient.* **Intended usage** *Single use, Prescription only.* **Intended part of the body/type of tissue applied to or interacted with** *The device will only be in contact with the operator´s skin or glove.* **Intended user profile** *Head and Neck Surgeon for placement of voice prosthesis. Trained clinician (eg physician, SLP) for replacement of voice prosthesis.* **Intended conditions of use** *Placement of voice prothesis is performed at the time of, and in the environment of, tracheoesophageal puncture.* *Replacement of voice prosthesis is performed in outpatient hospital settings, on average 4 times per year.*
Contraindications:	*None.*
CE Mark:	*Yes. Devices are CE-marked.*
GMDN code:	*63307 (Tracheoesophageal speech valve capsule mounting cap)*
Sterilization:	*Non-sterile*
Raw material:	*Polyamide PA2200*
Latex information:	*Not manufactured with natural rubber latex*
Biological origin:	*The device is not manufactured with materials derived from human or animal source.*
Handling and storage:	*Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.*
Waste handling and disposal:	*Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.*
Hazardous components:	*None*
Expiration date:	*3 years after manufacturing.*

Product Information

Packaging: *10 pcs Provox TwistLock are packed in a plastic zipper bag and then in a cardboard box together with IFU.*

Product Information

Devices under Basic UDI-DI: *7331791-VPS-A-000-0009-SB*

REF	Name	UDI-DI
8030	*Provox TwistLock 17Fr*	*07331791012747*
8031	*Provox TwistLock 20Fr*	*07331791012754*
8032	*Provox TwistLock 22.5Fr*	*07331791012761*

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	*7331791-VPS-0-0EI-0002-2V*
Provox Capsule	*7331791-VPS-A-000-0000-RG*

Product Information

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Approved:	DD	Jon Berg - JONBER	2022-01-13 - 13:21
Released:	DD	Maria Persson - X-MARPER	2022-01-13 - 14:38

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Provox® Protector

Product description:

Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma. The Provox Protector is to be placed around the neck during the daytime to be an esthetic coverage and protect against items accidentally entering the tracheostoma. For hygienic reasons, the Provox Protector should be changed daily or sooner if required.

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Product Information

Document ID:	PF102-01-TechInfo	**Edition:**	04

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 Class I (1.1 rule 1)

Intended Use: Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma.

Use specifications:

Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population: Patients after a tracheostomy or laryngectomy. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

Intended usage: Reusable. Hand washing maximum three times and air dried.

Intended part of the body/type of tissue applied to or interacted with: Neck and upper body.

Intended user profile: Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

Intended conditions of use: The Provox Protector act as a protective and cosmetic cover of the tracheostoma for daytime use. Intended for use at home (indoor and outdoor), care facilities and hospitals and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Frequency of use: Daily

Contraindications: No identified or known contraindications

CE Mark: Yes, the devices are CE marked.

GMDN code: 31065 (Tracheostoma protector, reusable)

Sterilization: Non-sterile

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Product Information

Raw material:

Provox Protector
- Polyester mesh
- Polyurethane foam
- Polyester brushed

Provox Protector Slim
- Polyester mesh
- PP non-woven
- Polyester brushed

Provox Protector Air
- PE spacer mesh
- Cotton textile

Latex information: Not manufactured with natural rubber latex

Biological origin: The device is not manufactured with materials derived from human or animal source.

Handling and storage: Store the product dry and away from sunlight at room temperature. Temporary deviations within 2°C - 42°C are allowed.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging: Single packed in polyethylene bag and 10 pcs are packed in cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-TEX-0-000-0001-WN

REF	Name	UDI-DI
7385	Provox Protector Small White 10 pcs	07331791012815
7385	Provox Protector Small White 1 pc	07331791015892
7386	Provox Protector Large White 10 pcs	07331791012822
7386	Provox Protector Large White 1 pc	07331791015908
7387	Provox Protector Slim Small White 10 pcs	07331791012839
7387	Provox Protector Slim Small White 1 pc	07331791015915
7388	Provox Protector Slim Small Blue 10 pcs	07331791012846
7388	Provox Protector Slim Small Blue 1 pc	07331791015922
7389	Provox Protector Slim Large White 10 pcs	07331791012853
7389	Provox Protector Slim Large White 1 pc	07331791015939
7390	Provox Protector Slim Large Blue 10 pcs	07331791012860
7390	Provox Protector Slim Large Blue 1 pc	07331791015946
7391	Provox Protector Air Small White 10 pcs	07331791012877
7391	Provox Protector Air Small White 1 pc	07331791015953
7392	Provox Protector Air Small Blue 10 pcs	07331791012884
7392	Provox Protector Air Small Blue 1 pc	07331791015960
7393	Provox Protector Air Large White 10 pcs	07331791012891
7393	Provox Protector Air Large White 1 pc	07331791015977
7394	Provox Protector Air Large Blue 10 pcs	07331791012907
7394	Provox Protector Air Large Blue 1 pc	07331791015984

Large White

Small White

Air Large

Slim Large

Atos Medical AB Compatible products:
Not applicable